DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville, Maryland 20850

MAR 15 2002

**WARNING LETTER**

**VIA FEDERAL EXPRESS**

Michael Pappas, Ph.D., P.E.
President
Endotec Incorporated
20 Valley Street
South Orange, New Jersey 07079

Dear Dr. Pappas:

During an inspection conducted on August 20, 24, 27 and 29, and September 10, 2001, investigators from the Food and Drug Administration (FDA) collected information that revealed a serious regulatory problem involving the product known as the [redacted] which is made and distributed by your firm. Under the United States Federal law, the Federal Food, Drug, and Cosmetic Act (the Act), these products are considered devices because they are used to diagnose or treat a condition or to affect the structure or function of the body. Of the concerns raised by that inspection, this letter only addresses your procedures for "Surgeon Specials" and "Custom" devices, and the devices distributed to Drs. Buechel and Feldman under those procedures. This letter also provides an explanation of the authorities governing custom devices, in response to contentions made in Endotec's letter of February 8, 2002, and prior correspondence with the Office of Device Evaluation.

Federal law requires that manufacturers of medical devices obtain marketing approval or clearance for their products from the FDA before they may offer them for sale. This helps protect the public health by ensuring that new medical devices are shown either to be safe and effective or to be substantially equivalent to other devices legally marketed in this country. You do not possess a premarket approval or a cleared premarket notification for the [redacted] device. CDRH has specifically notified you that the [redacted] device is not substantially equivalent to a legally marketed class II or class I device, and thus that you must obtain an approved PMA before marketing that device. A Federal Register notice calling for the submission of PMA applications for devices of the same type as the

[redacted] device was published on September 27, 1996. See 21 C.F.R. § 888.3120.

Despite this lack of clearance or approval, FDA's inspection revealed that at least [redacted] devices have been shipped to Dr. Buechel and implanted and that [redacted] identical modified [redacted] devices have been shipped to Dr. Feldman and implanted as "surgeon specials" or "custom devices." Your approved [redacted] device does not cover these shipments. You provided some of the [redacted] units of the implant to Dr. Buechel before FDA approved the [redacted], and consequently, those devices are adulterated under section 501(f)(1)(A) of the Act. You also continued to provide Dr. Buechel with [redacted] devices after FDA approved an [redacted], even though he was not an investigator in the study. This activity violated the [redacted] regulation, 21 C.F.R. 812.43(b), and caused the device to be further adulterated under section 501(i) of the Act. Although Dr. Feldman was an [redacted] under the [redacted], the [redacted] identical modified [redacted] devices shipped to him were not the subject of an approved [redacted] supplement and do not fall within the exemption from PMA requirements provided by the [redacted] for the [redacted] device. Consequently, those devices were also adulterated under section 501(f)(1) of the Act, and violated the IDE regulation, 21 C.F.R. 812.35, causing them to be adulterated under section 501(i) of the Act as well.

FDA's inspection revealed that your company recorded the [redacted] devices shipped to Dr. Buechel and the ten devices shipped to Dr. Feldman as "surgeon's specials" or custom devices. Likewise, your correspondence with ODE appears to contend that distribution of these devices is legal not because such distribution is authorized by any approved PMA, IDE, or product clearance, but because such devices are custom devices exempt from the requirements of premarket notification under 21 C.F.R. 807.85. This position indicates a fundamental misunderstanding of the custom device provisions of the Act and implementing regulations.

The custom device exemption of section 520(b) of the Act extends a limited exemption to the mandatory performance standard requirements of section 514 of the Act and the PMA requirements of section 515 of the Act to devices that meet a narrow and specific set of statutory requirements. Among those requirements, a custom device must be intended for use by an individual patient named in a prescription and made in a special form for that patient or must be intended to meet the special needs of a particular health professional in the course of his professional practice. A special need is one that relates to unusual anatomical features of the individual physician for whom the device is produced, or to special needs of his or her practice that are not shared by other health professionals of the same specialty. A device that meets a need that is shared by others in the field is a device that can be tested through clinical investigations and can be subject to the PMA requirements in order to ensure that it is safe and effective. These requirements are to be narrowly construed and do not create an exemption from otherwise applicable statutory requirements.

By regulation, FDA has extended the concept of a custom device exemption to IDEs through provisions found at 21 C.F.R. 812.2(c)(7) and 812.3(b), and to premarket notifications under section 510(k), through the regulation at 21 C.F.R. 807.85. These exemptions are not mandated by statute. Neither the IDE nor premarket notification regulations exempts from its respective requirements a broader category of devices than 520(b) of the Act exempts from the requirements of a PMA. Consequently, a device that could not qualify for a custom device exemption from PMA under section 520(b) also cannot qualify from the exemption from premarket notification requirements provided by 21 C.F.R. § 807.85. (Nor can it qualify for an exemption from IDE requirements under 21 C.F.R. § 812.2(c)(7).)

The devices distributed to Drs. Buechel and Feldman do not meet the criteria for a custom device explained above and, therefore, are not exempt from compliance with the premarket notification requirements, the investigational device exemption regulations, or premarket approval requirements. The [redacted] devices distributed to Dr. Buechel and the [redacted] modified [redacted] devices distributed to Dr. Feldman are not intended for use by an individual patient named in a physician's order and made in a specific form for that patient. Nor are they intended to meet a particular anatomical need of either Dr. Buechel or Dr. Feldman, or a particular unique practice need of either Dr. Buechel or Dr. Feldman that is not shared by other physicians in their field. Indeed, the [redacted] device already is the subject of a clinical investigation and there can be no reason to warrant its use as a custom device outside the study protocol.

As already noted, 21 C.F.R. 807.85, on which you appear to place particular emphasis, extends only an exemption from the premarket notification requirements of section 510(k), and not to any other requirements under the Act. Any class III device remains subject to the requirement of a PMA, under section 515 of the Act, unless it can qualify for some other exemption from the requirements of section 515. As already indicated, the [redacted] device is a class III device, and it does not satisfy the requirements for a custom-device exemption from PMA requirements, as set forth in section 520(b) of the Act. To the extent that your correspondence with ODE suggests that you consider the modified [redacted] device that you have been producing and distributing to Dr. Feldman to be a separate device, that device is a new device, first marketed after 1976, and is classified into class III under section 513(f)(1) of the act. For the reasons explained above, it also does not qualify for the custom device exemption set forth in section 520(b).

The custom device provision was not meant to allow the circumvention of otherwise applicable provisions of the Act. You should know that this serious violation of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizing your product inventory, obtaining an injunction against further marketing of the product, or assessing civil money penalties. Also, other Federal agencies are informed about warning letters we issue,

such as this one, so that they may consider this information when awarding government contracts.

It is necessary for you to take action on this matter now. Please let this office know, in writing within fifteen (15) working days from the date that you receive this letter, the steps you are taking to correct the problem. We also ask that you explain how you plan to prevent this from happening again. If you need more time, let us know why, and when you expect to complete your correction. Please address your response to:

Ms. Erin Keith
Office of Compliance/Division of Enforcement III (HFZ-343)
Center for Devices and Radiological Health
Food and Drug Administration
2094 Gaither Road
Rockville, MD 20850

If you have any questions regarding this matter please feel free to contact Ms. Keith at the address above or at (301) 594-4659 extension 117, or fax (301) 594-4672. You may obtain general information about all of FDA's requirements for manufacturers of medical devices by contacting our Division of Small Manufacturers, International and Consumer Assistance at (301) 443-6597, or through the Internet at http://www.fda.gov.

Sincerely yours,

Larry D. Spears
Acting Director
Office of Compliance
Center for Devices and
Radiological Health

cc: Frederick F. Buechel, M.D.
Medical Director
Endotec, Inc.
20 Valley Street
South Orange, NJ 07079